DrugControl®

MULTI DrugControl
008Axxx / 008AxxxA* - MultiDip - One for all -

ulti med™

Test device for the simultaneous, qualitative detection of any combination of Amphetamine, Barbiturates, Buprenorphine, Benzodiazepines, Cocaine, EDDP, Ketamine, MDMA, Methamphetamine, Methadone, Opiates/Morphine, Phencyclidine, Tricyclic Antidepressants, Oxycodone, Propoxyphene and Marijuana.
A rapid screening test for detection of multiple drugs and drug metabolites in human urine.

***Including Specimen Validity Tests (S.V.T.) for Oxidants / PCC (Pyridinium Chlorochromate), Specific Gravity, pH, Nitrite, Glutaraldehyde and Creatinine.**
For professional in vitro diagnostic use only.

INTENDED USE

The ulti med Test is a specific arrangement of different lateral flow chromatographic immunoassays for the detection of following drugs and cut-off concentrations in human urine (other cut-off concentrations according to the recommendation of SAMHSA and NIDA on request):

TEST DEVICE	Calibrator / related compounds	Cut-off Limit Value [ng / mL]
Amphetamines (AMP 1000)	**D-Amphetamine**	**1000**
	L-Amphetamine	100000
	Phentermine	1250
	(+/-)- Methylenedioxyamphetamine (MDA)	1250
	PMA	625
	Tyramine	100000
Amphetamines (AMP 500)	**D-Amphetamine**	**500**
	L-Amphetamine	50000
	Phentermine	1250
	(+/-)- Methylenedioxyamphetamine (MDA)	625
	PMA	625
	Tyramine	100000
Amphetamines (AMP 300)	**D-Amphetamine**	**300**
	L-Amphetamine	30000
	(+/-)-Methylenedioxyamphetamine(MDA)	375
	Phentermine	1250
	PMA	625
	Tyramine	100000
Barbiturate (BAR 300)	**Secobarbital**	**300**
	Amobarbital	625
	Allobarbital	1250
	Alphenal	625
	Aprobarbital	188
	Butabarbital	94
	Butalbital	2500
	Butethal	200
	Cyclophenobarbital	400
	Pentobarbital	1000
	Phenobarbital	300
Buprenorphine (BUP 10)	**Buprenorphine**	**10**
	Buprenorphine Glucuronide	25
	Buprenorphine-3-ß -D-Glucuroniede	10
	Norbuprenorphine	50
	Norbuprenorphine-3-ß-D-Glucuroniede	100
Buprenorphine (BUP 5)	**Buprenorphine**	**5**
	Buprenorphine Glucuronide	25
	Buprenorphine-3- ß-D-Glucuroniede	5
	Norbuprenorphine	10
	Norbuprenorphine-3-ß-D-Glucuroniede	50
Benzodiazepines (BZO 300)	**Oxazepam**	**300**
	Alprolazam	125
	Bromazepam	625
	Chlordiazepoxide	2500
	Clobazam	63
	Clonazepam	2500
	Chlorazepate	3330
	Delorazepam	2500
	Desalkylflurazepam	250
	Diazepam	250
	Estazolam	5000
	Flunitrazepam	375
	Lorazepam	1250
	Lormetazepam	1250
	Midazolam	100000
	Nitrazepam	25000
	Norchlordiazepoxide	250
	Nordiazepam	500
	Sulindac	100000
	Temazepam	63
	Triazolam	5000
Cocaine (COC 300)	**Benzoylecogonine**	**300**
	Cocaine	1000
	Ecgonine	100000
Ecstasy (MDMA 500)	**3,4-Methylenedioxymethamphetamine (MDMA)**	**500**
	3,4-Methylenedioxyamphetamine (MDA)	2500
	3,4-Methylendioxyethylamphetamine (MDEA)	156
	Paramethoxyamphetamine (PMA)	50000
	Paramethoxymethamphetamine (PMMA)	10000
Ecstasy (MDMA 300)	**3,4-Methylenedioxymethamphetamine (MDMA)**	**300**
	3,4-Methylenedioxyamphetamine (MDA)	2000
	3,4-Methylendioxyethylamphetamine (MDEA)	130
	Paramethoxyamphetamine (PMA)	30000
	Paramethoxymethamphetamine (PMMA)	6000

TEST DEVICE	Calibrator / related compounds	Cut-off Limit Value [ng / mL]
EDDP (EDDP 300)	**EDDP**	**300**
	Meperidine	100000
	Methadone	100000
	Norfentanyl	100000
	Phencyclidine	100000
	Promazine	80000
	Promethazine	75000
	Prothipendyl	80000
	Prozine	37500
EDDP (EDDP 100)	**EDDP**	**100**
	Meperidine	100000
	Methadone	100000
	Norfentanyl	100000
	Phencyclidine	100000
	Promazine	50000
	Promethazine	25000
	Prothipendyl	50000
	Prozine	12500
Ketamine (KET 1000)	**Ketamine**	**1000**
	Norketamine	1000
	Dextromethorphan	500
	Dextrorphan tartrate	500
	D-Norpropoxyphene	31250
	EDDP	800
	Meperidine	12500
	Mephentermine hemisulfat salt	15625
	Methadone	50000
	D-Methamphetamine	12500
	3,4-Methylenedioxyethylamphetamine (MDEA)	25000
	Nordoxepin hydrochloride	25000
	Phencyclidine	5000
	Promazine	8000
	Promethazine	25000
Marijuana (THC 50)	**11-nor- Δ^9-THC-9-COOH**	**50**
	11-nor- Δ^9-THC-9-COOH	50
	Δ^8-THC	15000
	Δ^9-THC	15000
	Cannabinol	>20000
Methamphetamines (MET 1000)	**d-Methamphetamine**	**1000**
	Chloroquine	25000
	Fenfluramine	12500
	l-Methamphetamine	10000
	Mephentermine hemisulfate salt	31250
	(+/-) 3,4-Methylenedioxy-n-ethylamphetamine (MDEA)	50000
	(+/-)3,4-Methylenedioxymethamphetamine (MDMA)	313
	PMMA	625
Methamphetamines (MET 500)	**d-Methamphetamine**	**500**
	Chloroquine	12500
	Fenfluramine	25000
	l-Methamphetamine	3125
	Mephentermine hemisulfate salt	25000
	(MDEA)	12500
	(MDMA)	1875
	PMMA	625
Methamphetamines (MET 300)	**d-Methamphetamine**	**300**
	Chloroquine	7500
	Fenfluramine	12500
	l-Methamphetamine	2250
	Mephentermine hemisulfate salt	20000
	MDEA	3125
	MDMA	313
	PMMA	625
Methadone (MTD 300)	**Methadone**	**300**
	(-)-alpha-methadol	2000
Morphine (MOR/OPI 300)	**Morphine**	**300**
	Acetylcodeine	150
	Buprenorphine	3125
	Codeine	250
	Diacetyl Morphin	250
	Dihydrocodeine	586
	Ethylmorphine	200
	Hydrocodone	12500
	Hydromorphone	12500
	6-Monoacetylmorphine	250
	Morphine-3-glucuronid	2500
	Nalorphine	25000
	Thebaine	25000

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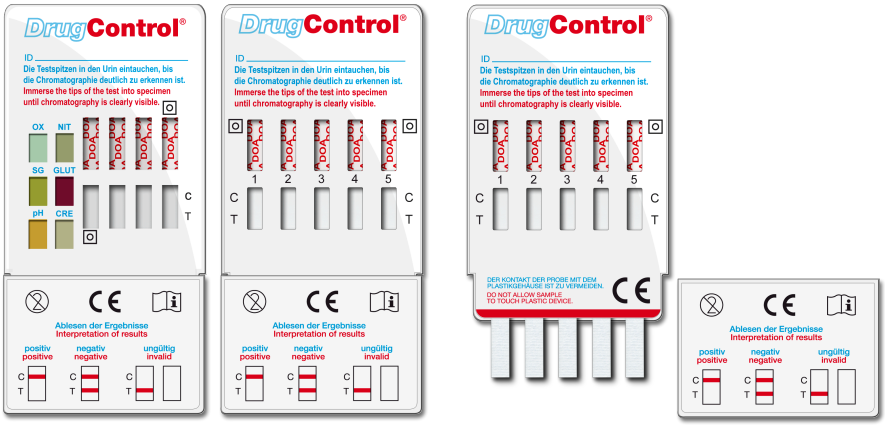
TEST DEVICE	Calibrator / related compounds	Cut-off Limit Value [ng / mL]
Opiates (OPI 2000)	**Morphine**	**2000**
	Acetylcodeine	1563
	Buprenorphine	25000
	Codeine	500
	Diacetyl Morphin (Heroin)	1250
	Dihydrocodeine	1563
	Ethylmorphine	800
	Hydrocodone	50000
Oxycodone (OXY 100)	**Oxycodone**	**100**
	Hydrocodone	25000
	Hydromorphone	50000
	Naloxone	50000
	Oxymorphone	250
Phencyclidine (PCP 25)	**Phencyclidine**	**25**
	Hydrocodone	12500
	Hydromorphone	6250

TEST DEVICE	Calibrator / related compounds	Cut-off Limit Value [ng / mL]
Propoxyphene (PPX 300)	**D-Propoxyphene**	**300**
	D-Norpropoxyphene	5000
Tricyclic Antidepressants (TCA 1000)	**Nortryptiline HCl**	**1000**
	Amitryptiline	1500
	Chlomipramine	100000
	Cyclobenzaprine	12500
	Desipramine	188
	Doxepin	2000
	Imipramine	2500
	Maprotiline	750
	Nordoxepin	500
	Opipramol	1563
	Promazine	1000
	Promethazine	6250
	Prothipendyl	25000
	Protryptyline	6250
	Prozine	1250
	Trimipramine	100000

These assays provide only preliminary analytical test results. An alternate chemical method must be used in order to obtain a confirmed analytical result. Gas chromatography/mass spectrometry (GC/MS) or liquid chromatography/mass spectrometry (LC/MS) are the preferred confirmatory methods. Clinical consideration and professional judgement should be applied to any drug of abuse test result, particularly when preliminary positive results are used.



Test with Adulteration | Test without Adulteration

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PRINCIPLE

The ulti med **MULTI** ***DrugControl*** Test is an immunoassay in which chemically labelled drugs (drug-protein conjugates) compete for limited antibody binding sites with drugs which may be present in urine. The test device contains membrane strips which are pre-coated with drug-protein conjugates on the test band(s). Each strip, the drug antibody-colloidal gold conjugate pad is placed at one end of the membrane. In the absence of drug in the urine, the solution of the colored antibody-colloidal gold conjugate move along with the sample solution upward chromatographically by capillary action across the membrane to the immobilized drug-protein conjugate zone on the test band region. The colored antibody-gold conjugate then attach to the drug-protein conjugates to form visible lines as the antibody complex with the drug conjugate. Therefore, the formation of the visible precipitant in the test zone occurs when the test urine is negative for the drug. When the drug is present in the urine, the drug/metabolite antigen competes with drug-protein conjugate on the test band region for the limited antibody. When a sufficient concentration of the drug is present, it will fill the limited antibody binding sites. This will prevent attachment of the colored antibody (drug-protein conjugate)-colloidal gold conjugate to the drug-protein conjugate zone on the test band region. Therefore, absence of the color band on the test region indicates a positive result.

A control band with a different antigen/antibody reaction is added to the immunochromatographic membrane strip at the control region (C) to indicate that the test has performed properly. This control line should always appear regardless of the presence of drug or metabolite. If the control line does not appear the test device should be discarded.

ADULTERATION

Adulteration is the tampering of a urine specimen with the intention of altering the test results. The use of adulterants can cause false negative results in drug tests by either interfering with the screening test and/or destroying the drugs present in the urine. Dilution may also be employed in an attempt to produce false negative drug test results.
One of the best ways to test for adulteration or dilution is to determine certain urinary characteristics such as

- Oxidants/PCC
- Specific Gravity
- pH
- Nitrite
- Glutaraldehyde
- Creatinine

PRECAUTIONS

- For professional in vitro diagnostic use only.
- Do not use after the expiration date.
- The test device should remain in the sealed pouch until use.
- Do not moisten nitrocellulose membrane with urine samples.
- Immerse tips of test strips for at least 10-15 seconds in the urine specimen.
- Avoid cross-contamination of urine samples by using a new specimen collection container for each urine sample
- All specimens should be considered potentially hazardous and handled in the same manner as an infectious agent
- The used test device should be discarded according to federal state and local regulations.

STORAGE AND STABILITY

The ulti med ***DrugControl*** can be stored at room temperature or refrigerated (2 – 30 °C).
The test is stable through the expiration date printed on the sealed pouch. The product is humidity-sensitive and should be used immediately after being opened.

- Do not freeze.
- Do not use beyond the expiration date.

SPECIMEN COLLECTION AND PREPARATION

The urine specimen must be collected in a clean and dry container. Urine collected at any time of the day may be used. Urine specimens exhibiting visible precipitates should be centrifuged, filtered, or allowed to settle to obtain a clear specimen for testing. Urine specimens may be stored at 2 - 8°C for up to 48 hours prior to testing. For long-term storage, specimens may be frozen and stored below -20 °C. Frozen specimens should be thawed and mixed before testing.

MATERIALS PROVIDED

- Multi test device
- Package insert
- For tests with adulteration:
  SVT/Adulterant color chart

MATERIALS REQUIRED BUT NOT PROVIDED

- Specimen collection container
- Timer

Dip the **MULTI** ***DrugControl***
into urine specimen

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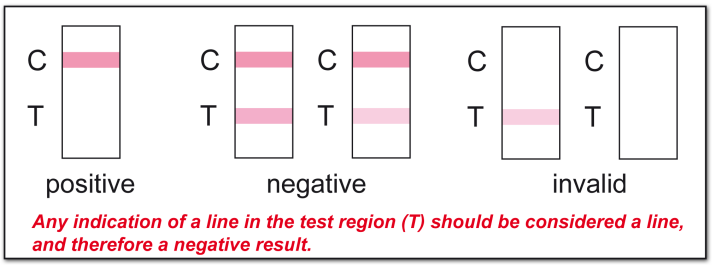
DIRECTIONS FOR USE

1. Allow the urine specimen, test device, and / or controls to reach room temperature (15 – 30 °C) prior to testing.
2. Bring pouch to room temperature before opening it.
3. Remove the Multi test from the sealed pouch and use it as soon as possible.
4. **Immerse the tips of the Multi test vertically in the urine specimen for at least 10-15 seconds.**
5. Do not pass the maximum line (dipping line) on the test when immersing the tips of the Multi test.
6. Place the test on a non-absorbent flat and clean surface. Start the timer and wait for the red lines to appear.
7. Read the adulteration strip between 3 and 5 minutes.
8. The result should be read at 5 minutes. Do not interpret the result after 8 minutes.

INTERPRETATION OF RESULTS



Any indication of a line in the test region (T) should be considered a line, and therefore a negative result.

Negative:* Two lines appear in each window. One red line should be in the control region (C), and another apparent red or pink line should be in the test region (T). This negative result indicates that the concentrations of the substances detectable with the corresponding test are below the cut-off concentration (substances and cut-off concentrations see table on page 1) or that they are not present.

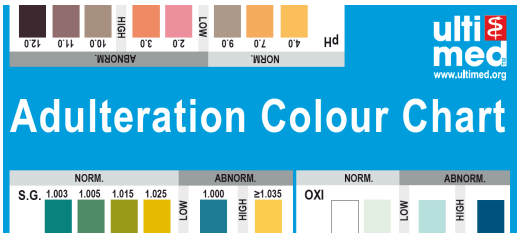
Positive: One red line appears in the control region (C). No line appears in the test region (T). This positive result indicates that the concentration of at least one of the substances detectable with the corresponding test exceeds the cut-off concentration (substances and cut-off concentrations see table on page 1).

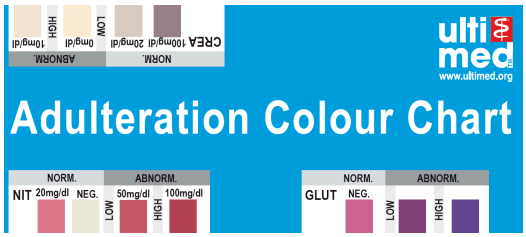
Invalid: Control line fails to appear. Insufficient specimen volume or incorrect procedural techniques are the most likely reasons for control line failure. Review the procedure and repeat the test using a new test device. If the problem persists, discontinue using the lot immediately and contact distributor / manufacturer.

* **Note:** The shade of red in the test line region (T) may vary, but it should be considered negative whenever there is even a faint pink line.

ADULTERANT INTERPRETATION

Semi-quantitative results are obtained by visually comparing the reacted color blocks on the strips to the printed colour blocks on the colour chart. No instrumentation is required.





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SUMMARY AND EXPLANATION OF THE TEST

The ulti med *DrugControl* Test is a competitive immunoassay utilizing highly specific reactions between antibodies and antigens for the detection of multiple drugs and drug metabolites in human urine. The ulti med Drug of Abuse Test is a rapid urine screening test that utilizes monoclonal antibodies to selectively detect elevated levels of specific drugs in urine without the use of an instrument.

Amphetamine (AMP): Amphetamine is a potent central nervous system stimulant currently prescribed to treat Attention-Deficit/Hyperactivity Disorder (ADHD) and narcolepsy. Acute higher doses induce euphoria, alertness and sense of increased energy and power.

Barbiturate (BAR): Barbiturates are central nervous system depressants. They are used therapeutically as sedatives, hypnotics, and anticonvulsants. Barbiturates are almost always taken orally as capsules or tablets. The effects resemble those of intoxication with alcohol. Chronic use of Barbiturates leads to tolerance and physical dependence. Short acting Barbiturates taken at 400 mg/day for 2-3 months produce a clinically significant degree of physical dependence. Withdrawal symptoms experienced during periods of drug abstinence can be severe enough to cause death.

Benzodiazepines (BZD): Benzodiazepines are central nervous system (CNS) depressants commonly prescribed for the short-term treatment of anxiety and insomnia. In general, benzodiazepines act as hypnotics in high doses, as anxiolytics in moderate doses and as sedatives in low doses. The use of benzodiazepines can result in drowsiness and confusion. Psychological and physical dependence on benzodiazepines can develop if high doses of the drug are given over a prolonged period. Benzodiazepines are taken orally or by intramuscular or intravenous injection, and are extensively oxidized in the liver to metabolites.

Buprenorphine (BUP): Buprenorphine is a potent analgesic often used in the treatment of opioid addiction. The drug is sold under the trade names SubutexTM, BuprenexTM,TemgesicTM and SuboxoneTM, which contain Buprenorphine HCl alone or in combination with Naloxone HCl. Therapeutically, Buprenorphine is used as a substitution treatment for opioid addicts. Substitution treatment is a form of medical care offered to opiate addicts (primarily heroin addicts) based on a similar or identical substance to the drug normally used. In substitution therapy, Buprenorphine is as effective as Methadone but demonstrates a lower level of physical dependence. The plasma half-life of Buprenorphine is 2-4 hours. While complete elimination of a single-dose of the drug can take as long as 6 days, the detection window for the parent drug in urine is thought to be approximately 3 days.

Cocaine (COC): Cocaine is a potent central nervous system stimulant and a local anesthetic found in the leaves of the coca plant. The psychological effects induced by using cocaine are euphoria, confidence and sense of increased energy. These psychological effects are accompanied by increased heart rate, dilation of the pupils, fever, tremors and sweating.

EDDP (EDDP): Methadone (MTD) is a synthetic analgesic drug that is originally used in the treatment of narcotic addicts. Among the psychological effects induced by using methadone are analgesia, sedation and respiratory depression. Overdose of methadone may cause coma or even death. It is administered orally or intravenously and is metabolized in the liver. The kidneys are a major route of methadone excretion. Methadone has a biological half-life of 16-50 hours. EDDP (2-Ethyliden-1,5-Dimethyl-3,3-Diphenylpyrrolidine) is the most important metabolite of methadone. It is excreted into the bile and urine together with the other metabolite EMDP (2-Ethyl-5-Methyl-3,3-Diphenylpyrrolidine). EDDP is formed by N-demethylation and cyclization of methadone in the liver. The part of the unchanged excreted methadone is variable and depends on the urine's pH value, dose and the patient's metabolism. Therefore, the detection of the metabolite EDDP instead of methadone itself is useful, because interferences of the patient's metabolism are avoided.

Ketamine (KET): Ketamine is a derivative of phencyclidine. It is used medically as a veterinary and human anaesthetic since 1970. About 90 percent of the ketamine legally sold is intended for veterinary use. It can be injected or snorted, but is sometimes sprinkled on tobacco or marijuana and smoked. Ketamine is frequently used in combination with other drugs, such as ecstasy, heroin or cocaine. Ketamine is also known as "special K" or "vitamin K." Certain doses of Ketamine can cause dream-like states and hallucinations. In high dose, ketamine can cause delirium, amnesia, impaired motor function, high blood pressure, depression, and potentially fatal respiratory problems. Ketamine is metabolized in the liver and excreted through the kidney.

Marijuana (THC-COOH): Tetrahydrocannabinol is generally accepted to be the principle active component in marijuana. Once in the blood stream, ∆9 - THC (parent) is mainly quickly metabolized into THC metabolites in the liver. These psycho inactive THC metabolites are stored in the fatty tissue to some extent and are then discharged in urine over a period of between a few days to several weeks following consumption, where it is detected as THC-COOH (metabolite) in a positive test result. When ingested or smoked, it produces euphoric effects. Abusers exhibit central nervous system effects, altered mood and sensory perceptions, loss of coordination, impaired short term memory, anxiety, paranoia, depression, confusion, hallucinations and increased heart rate.

Methadone (MTD): Methadone is a synthetic analgesic drug originally used for the treatment of narcotic addiction. In addition to use as a narcotic agonist, methadone is being used more frequently as a pain management agent. The psychological effects induced by using methadone are analgesia, sedation, and respiratory depression.

Methamphetamine (MET): Methamphetamine is a potent central nervous system stimulant. Acute higher doses induce euphoria, alertness, and sense of increased energy and power. More acute responses produce anxiety, paranoia, psychotic behaviour, and cardiac dysrhythmias.

Ecstasy (MDMA): MDMA is an abbreviation for the chemical methylenedioxymethamphetamine MDMA. It has street many name including Ecstasy, X, XTC, E, Love Doves, Clarity, Adam, Disco Biscuits and Shamrocks, etc. it is a stimulant with hallucinogenic tendencies, described as an empathogen as it releases mood-altering chemicals, such as cartooning and L-dopa, in the brain and may generate feelings of love and friendliness. MDMA is a Class A drug, in the same category as heroin and cocaine. The adverse effects of MDMA use include elevated blood pressure, hyperthermia, anxiety, paranoia, and insomnia. Overdoses of MDMA can be fatal, often resulting in heart failure or heart stoke.
MDMA belongs to a family of man-made drugs; its relatives include MDA (methylenedioxy MDMA), the parent drug of MDMA, and MDEA (methylenedioxyethyl MDMA), also know as EVE. They all share the MDMA-like effects. MDMA is administered either by oral ingestion or

intravenous injection. MDMA tablets come in different sizes and colors, and often have logos such as doves on them. Its clinical dose is 50-100mg ; the threshold toxic dose is 500mg. The effects of MDMA begin 30 minutes after intake.

Opiates/Morphine (OPI/MOR): Opiates such as heroin, morphine, and codeine, are central nervous system (CNS) depressants. The use of opiates at high doses produces euphoria and release from anxiety. Physical dependence is apparent in users and leads to depressed coordination, disrupted decision making, decreased respiration, hypothermia and coma.

Oxycodone (OXY): Oxycodone is a semi-synthetic opioid with a structural similarity to codeine. The drug is manufactured by modifying thebaine, an alkaloid found in the opium poppy. Oxycodone, like all opiate agonists, provides pain relief by acting on opioid receptors in the spinal cord, brain, and possibly directly in the affected tissues. Oxycodone is prescribed for the relief of moderate to high pain under the well-known pharmaceutical trade names of OxyContin®, Tylox®, Percodan® and Percocet®. While Tylox®, Percodan® and Percocet® contain only small doses of oxycodone hydrochloride combined with other analgesics such as acetaminophen or aspirin, OxyContin consists solely of oxycodone hydrochloride in a time-release form. Oxycodone is known to metabolize by demethylation into oxymorphone and noroxycodone.

Phencyclidine (PCP): Phencyclidine is an arylcyclohexylamine that was originally used as an anesthetic agent and a veterinary tranquilizer. Phencyclidine can produce hallucinations, lethargy, disorientation, loss of coordination, trance-like ecstatic states, a sense of euphoria and visual distortions. It has many street names, such as “angel dust” and “crystal cyclone”, etc. Phencyclidine can be administered orally, by nasal ingestion, smoking, or intravenous injection. It is metabolized in the liver and excreted through the kidneys.

Propoxyphene (PPX): Propoxyphene or Dextropropoxyphene is a narcotic analgesic compound with a structural similarity to methadone. It is prescribed in the United States for the relief of moderate pain. DarvocetTM, one of the most common brand names for the drug, contains 50-100 mg of propoxyphene napsylate and 325-650 mg of acetaminophen. Physiological effects of propoxyphene include respiratory depression. Propoxyphene is metabolized in the liver to yield norpropoxyphene. Norpropoxyphene has a longer half-life (30 to 36 hours) than that of propoxyphene (6 to 12 hours). Norpropoxyphene demonstrates substantially less central-nervous system depression than propoxyphene, but shows a greater local anesthetic effect.

Tricyclic Antidepressants (TCA): TCA are commonly used for the treatment of depressive disorder. TCA overdose can result in profound central nervous system depression, cardiotoxicity and anticholinergic effects. TCA overdose is the most common cause of death from preciption drugs. TCA are taken orally or sometimes by injection. TCA are metabolized in the liver. Both TCA and their metabolites are excreted in urine mostly in the form of metabolites for up to ten days.

Adulteration

Oxidants/PCC (Pyridinium chlorochromate) tests for the presence of oxidizing agents such as bleach and hydrogen peroxide. Pyridinium Chlorochromate is a commonly used adulterant. Normal human urine should not contain oxidants or PCC.

Specific gravity tests for sample dilution. The normal range is from 1.003 to 1.030. Values outside this range may be the result of specimen dilution or adulteration.

PH tests for the presence of acidic or alkaline adulterants in urine. Normal pH levels should be in the range of 4.0 to 9.0. Values outside of this range may indicate the sample has been altered.

Nitrite tests for commonly used commercial adulterants such as Klear or Whizzies. They work by oxidizing the major cannabinoid metabolite THC-COOH. Normal urine should contain no trace of nitrite. Positive results generally indicate the presence of an adulterant.

Glutaraldehyde tests for the presence of an aldehyde. Adulterants such as UrinAid and Clear Choice contain glutaraldehyde which may cause false negative screening results by disrupting the enzyme used in some immunoassay tests. Glutaraldehyde is not normally found in urine; therefore, detection of glutaraldehyde in a urine specimen is generally an indicator of adulteration.

Creatinine is a waste product of creatine, an amino acid contained in muscle tissue and found in urine[6] A person may attempt to foil a test by drinking excessive amounts of water or diuretics such as herbal teas to “flush” the system. Creatinine and specific gravity are two ways to check for dilution and flushing, which are the most common mechanisms used in an attempt to circumvent drug testing. Low creatinine and specific gravity levels may indicate dilute urine. The absence of creatinine (< 5 mg/dL) is indicative of a specimen not consistent with human urine.

QUALITY CONTROL

Internal procedural controls are included in the test. A colored band appearing in the control region (C) is considered an internal positive procedural control, confirming sufficient specimen volume and correct procedural technique.
External controls are not supplied with this kit. It is recommended that positive and negative controls be tested as a good laboratory practice to confirm the test procedure and to verify proper test performance.

LIMITATIONS

1. The ulti med ***DrugControl*** Test provides only a qualitative, preliminary analytical result. A secondary analytical method must be used to obtain a confirmed result. Gas chromatography/mass spectrometry (GC/MS) is the preferred confirmatory method.
2. There is a possibility that technical or procedural errors, as well as other interfering substances in the urine specimen may cause erroneous results.
3. Adulterants, such as bleach and/or alum, in urine specimens may produce erroneous results regardless of the analytical method used. If adulteration is suspected, the test should be repeated with another urine specimen and a new test device.
4. A Positive result does not indicate intoxication of the donor, the concentration of drug in the urine, or the route of drug administration.
5. A Negative result may not necessarily indicate drug-free urine. Negative results can be obtained when drug is present but below the cut-off level of the test.
6. Test does not distinguish between drugs of abuse and certain medications.
7. A positive test result may be obtained from certain foods or food supplements.

ADULTERATION LIMITATIONS

1. The adulteration tests included with this product are meant to aid in the determination of abnormal specimens. While comprehensive, these tests are not meant to be an “all-inclusive” representation of possible adulterants.
2. Oxidants/PCC: Normal human urine should not contain oxidants or PCC. The presence of high levels of antioxidants in the specimen, such as ascorbic acid, may result in false negative results for the oxidants/PCC pad.
3. Specific Gravity: Elevated levels of protein in urine may cause abnormally high specific gravity values.
4. Nitrite: Nitrite is not a normal component of human urine. However, nitrite found in urine may indicate urinary tract infections or bacterial infections. Nitrite levels of > 20 mg/dL may produce false positive glutaraldehyde results.
5. Glutaraldehyde: Is not normally found in urine. However certain metabolic abnormalities such as ketoacidosis (fasting, uncontrolled diabetes or high-protein diets) may interfere with the test results.
6. Creatinine: Normal creatinine levels are between 20 and 350 mg/dL. Under rare conditions, certain kidney diseases may show dilute urine.

REAGENTS

The test contains a membrane strip coated with drug bovine protein antigen conjugate on the test line, a goat anti-rabbit antibody at the control line, and a dye pad which contains monoclonal antibody and rabbit antibody gold complex.

PERFORMANCE CHARACTERISTICS

Specificity

The specificity for the ulti med *DrugControl* Test has been tested by adding various drugs, drug metabolites, and other compounds that likely to be present in drug-free normal human urine. The Test performance at cut-off point are not affected when pH range of urine specimens is at 3.0 to 8.5 and specific gravity range of urine specimens is at near 1.005 to 1.03. The compounds listed on page 1 were found to produce positive results when tested at levels greater than the concentrations (in ng/ml) listed on page 1.

Accuracy of the ulti med *DrugControl* Test was established by running urine sample against GC/MS specification.

% Agreement with GC/MS									
	AMP 1000	AMP 500	AMP 300	BAR	BZO	COC	EDDP 300	EDDP 100	KET
Positive Agreement	95.8	94.4	94.8	97.8	95.3	98.2	98.6	98.6	98.0
Negative Agreement	>99	>99	>99	98.1	92.9	98.1	>99	>99	98.6
Total Results	98.1	97.2	97.6	98.0	93.9	98.1	99	99.1	98.3

% Agreement with GC/MS									
	MDMA 500	MDMA 300	MET/ 1000	MET/ 500	MET/ 300	MTD	OPI/ 2000	OPI/MOR 300	PCP
Positive Agreement	>99	97.4	96.8	97.0	96.8	96.1	97.6	96.8	97.8
Negative Agreement	>99	>99	>99	>99	>99	>99	98.4	97.9	>99
Total Results	>99	98.4	98.3	98.3	98.4	98.1	98.1	97.3	98.9

% Agreement with GC/MS						% Agreement with LC/MS	
	TCA	THC	PPX	OXY		BUP/ 10	BUP/ 5
Positive Agreement	92.1	96.8	97,8	96.1		>99	>99
Negative Agreement	>99	98.3	>99	>99		>99	>99
Total Results	96.8	97.5	99	98.1		>99	>99

Analytical Sensitivity

The sensitivity was determined by tested GC/MS confirmed controls to the concentration at negative, -50% cut-off, -25% cut-off, cut-off, +25% cut-off, +50% cut-off and 3 times of cut-off. The results are summarized below:

Drug concentration Cut-off Range	n	AMP/ 1000		AMP/ 500		AMP/ 300		BAR		BUP/ 10		BUP/ 5		BZO		COC	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0 % Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-50 % Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-25 % Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cut-off	50	16	34	36	14	30	20	11	39	22	28	21	29	17	33	11	39
+25 % Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+50 % Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
3X Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug concentration Cut-off Range	n	EDDP/ 300		EDDP/ 100		KET		MDMA		MDMA 300		MET/ 1000		MET/ 500		MET/ 300	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0 % Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-50 % Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-25 % Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cut-off	50	26	24	25	25	16	34	25	25	26	24	23	27	40	10	35	15
+25 % Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

+50 % Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
3X Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Drug concentration Cut-off Range	n	MTD		OPI/ 2000		OPI/MOR 300		PCP		TCA		THC		PPX		OXY	
		-	+	-	+	-	+	-	+	-	+	-	+	-	+	-	+
0 % Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-50 % Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
-25 % Cut-off	50	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0
Cut-off	50	6	44	13	37	18	32	9	41	9	41	17	33	22	28	19	31
+25 % Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
+50 % Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50
3X Cut-off	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50	0	50

Non Cross-Reacting Compounds

The following compounds were found not to cross-react when tested at concentrations at 100 µg/mL.

Acetaminophen
Acetone
Albumin
Amitriptyline
Ampicillin
Aspartame
Aspirin
Atropine
Benzocaine
Bilirubin
Caffeine
Chlorpheniramine
Creatinine
Dextrorphan tartrate
4-Dimethylaminoantipyrine
Dopamine
(-)-Ephedrine
(+)-Ephedrine
Erythromycin
Ethanol
Furosemide
Guaiacol Glyceryl Ether
Hemoglobin
Ibuprofen
Imipramine (Exept TCA)
(+/-)-Isoproterenol
Lidocaine
N-Methyl-Ephedrine
Oxalic acid
Penicillin-G
Pheniramine
Phenothiazine
L-Phenylephrine
b-Phenylethylamine
Procaine
Quinidine
Ranitidine
Vitamin C

LIMITATIONS

It is impossible to check any and all - other than those drugs mentioned in the product insert - for cross-reactivity or any other influences to the to be detected drug of abuse (DOA).
If the patient takes a „cocktail“ of several different drugs or medication cannot be excluded that a non-reproducible cross-reaction can falsified the test result.

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	Manufacturer		Contents sufficient for <n> tests
IVD	For in vitro diagnostic use only	LOT	Lot. no.
	For single use only		Expiration date
	Read instructions for use		Store at
	Keep away from direct sunlight		

This operating manual conforms to the latest technology / revision. Subject to change without prior notice!

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